

Applicants previously sought, pursuant to 37 C.F.R. §§ 1.607 and 1.608(a), to provoke an interference between the captioned application and U.S. Patent No. 5,811,523 (the “’523 patent”), entitled “Antibodies To Natural Killer Stimulatory Factor,” which issued September 22, 1998 from application Serial No. 956,240, filed October 22, 1997. A single count was proposed directed to an antibody which specifically reacts with natural killer cell stimulatory factor (“NKSF”) cytokine, which is also known as cytotoxic lymphocyte maturation factor (“CLMF”) and interleukin-12 (“IL-12”). Each of the ’523 patent claims and the claims pending in the captioned application are drawn to antibodies directed against IL-12.¹

In a Communication, mailed August 21, 2000, the Examiner indicated that Applicants’ request for interference had been granted, all rejections of Claims 33-38 were withdrawn, Claims 33-38 were found allowable and *ex parte* prosecution was suspended due to a potential interference.

In the instant Office Action, however, prosecution has been re-opened, and the previous rejections have been “maintained.” The basis for “maintaining” the rejections is a contention that declaration of the interference requires a showing under 37 C.F.R. § 1.608(b). Although the Examiner previously considered and granted Applicants’ request for interference, no reasoning is provided explaining why a statement under 37 C.F.R. § 1.608(a) is now deemed unacceptable.

As summarized below, for the reasons originally acknowledged by the Examiner, the statement under 37 C.F.R. § 1.608(a), of record, remains acceptable and sufficient for declaration of the interference. Entry of the remarks made herein is respectfully requested.

¹ The cytokine has come to be known in the art as IL-12. The ’523 patent refers to IL-12 as NKSF, and the captioned application refers to the cytokine as CLMF.

The Rejections Under 35 U.S.C. §§ 102(e) or 103(a) Should be Withdrawn

Claims 33-38 are rejected under 35 U.S.C. § 102(e) as anticipated by, and/or under 35 U.S.C. § 103(a) as obvious in view of, the '523 patent. As Applicants have explained in detail during the prosecution of the captioned application, and as summarized below, the effective filing dates of the captioned application and the '523 patent for the invention of the proposed count are within three months of each other. Although the Examiner originally found these reasons persuasive, the Examiner has now, with no explanation, determined that a showing under 37 C.F.R. § 1.608(b) is necessary. As discussed below, however, the statement under 37 C.F.R. § 1.608(a), of record, remains sufficient for the rejections to be overcome and for an interference to be declared.

The Effective Filing Dates of the '523 Patent and the Captioned Application for the Proposed Count Are Within Three Months of Each Other

The captioned application claims priority through a series of continuation, divisional and continuation-in-part applications to December 22, 1989. Applicants have demonstrated that the captioned application should be accorded benefit of the August 27, 1990 filing date of priority application Serial No. 572,284 (the "'284 application") for the invention of the proposed count.

The '523 patent claims priority through a series of continuation, divisional and continuation-in-part applications to November 10, 1988. However, the claims of the '523 patent should only be accorded benefit of the September 18, 1990 filing date of '523 patent priority application Serial No. 584,941 (the "'941 application") for the invention of the proposed count.

Thus, for the invention of the proposed count, the effective filing date of the captioned application is August 27, 1990, which is within three months of the September 18, 1990 effective filing date of the '523 patent.

On September 22, 1999, Applicants filed a Request Under 37 C.F.R. §§ 1.607 and 1.608(a) for Interference With A Patent (“Request”), seeking to have an interference declared between the captioned application and the ’523 patent. In the Request, Applicants proposed a single count directed to an antibody that specifically reacts with NKSF, which, as discussed above, is also known as CLMF and IL-12. Applicants explained why each of the claims of the ’523 patent (Claims 1-7) and the captioned application (Claims 33-38) should be designated as corresponding to the proposed count.

In order to receive the benefit of an earlier application in an interference, the earlier application must meet the requirements of 35 U.S.C. § 112, first paragraph, for an embodiment within the interference count. *Hunt v. Treppschuh*, 187 USPQ 426, 429 (C.C.P.A. 1975); *Weil v. Fritz*, 196 USPQ 600, 608 n.16 (C.C.P.A. 1978).

The Request set forth with particularity the reasons why the claims of the captioned application are entitled to the August 27, 1990 filing date of Applicants’ ’284 application (pages 41-45) for the count, while the claims of the ’523 patent are only entitled to the September 18, 1990 filing date of the ’941 application (pages 17-41) for the count. In particular, the Request explained in detail how the specification of Applicants’ ’284 application fully describes the antibodies claimed in the captioned application, and also teaches how to make and use the claimed antibodies without having to resort to undue experimentation.

Likewise, the Request set forth in detail the reasons why the ’523 patent priority applications filed prior to the ’941 application fail to disclose a practical use for the claimed antibodies and also fail to either describe or enable the claimed antibodies. The arguments presented in the Request were accompanied by a supporting Declaration of David H. Presky, an expert in the IL-12 field.

Pursuant to 37 C.F.R. § 1.608(a), a statement that there is a basis for judgment in favor of Applicant is sufficient for declaration of the interference, since the effective filing dates of the captioned application and the '523 patent for the proposed count are within three months of each other. Accordingly, a Declaration of Thomas E. Friebe Under 37 C.F.R. § 1.608(a) was filed concurrently with the Request.

On January 24, 2000, an Office Action was mailed rejecting the claims of the captioned application under 35 U.S.C. §§ 102(e) or 103 in view of the '523 patent. The Examiner acknowledged the Request but contended that a showing under 37 C.F.R. § 1.608(b) was required prior to declaration of the interference because the alleged effective filing date of the '523 patent antedates that of the captioned application by more than three months.

On April 17, 2000, the Examiner held an interview with the undersigned and Examiner Michael Woodward, then the Group Interference Specialist. As the Interview Summary (Paper No. 6) points out, it was agreed that Applicants would submit a second Request Under 37 C.F.R. §§ 1.607 and 1.608(a) for Interference With A Patent ("Second Request") to seek to have an interference declared between the captioned application and the '523 patent by demonstrating the reasons why the '523 priority applications prior to September 18, 1990 fail to support enablement and/or utility of the subject matter of the count, thereby making September 18, 1990 the effective filing date of the '523 patent, *i.e.*, an effective filing date that is within three months of the effective filing date of the captioned application.

On July 24, 2000 Applicants submitted the Second Request. The Second Request reiterated the reasoning why the claims of the captioned application are entitled to a August 27, 1990 effective filing date (pages 40-44), and why the '523 patent priority

applications filed prior to September 18, 1990 fail to describe or enable the claimed antibodies and also fail to state a practical utility for the antibodies (pages 16-40). The Second Request was accompanied by a Second Declaration of James H. Presky supporting the arguments made in the Second Request. The Second Request was also accompanied by a Second Declaration of Thomas E. Friebe Under 37 C.F.R. § 1.608(a).

On August 21, 2000, a Communication was mailed indicating that the Examiner had considered and found persuasive Applicants' reasoning for why the statement under 37 C.F.R. § 1.608(a), of record, is sufficient for withdrawal of the rejections and declaration of the interference. In particular, the Communication stated that the Second Request had been considered and granted, and that the Second Declaration of James H. Presky had been considered and had been found persuasive. The Communication stated that the previous rejections under 35 U.S.C. §§ 102(e) and 103 had been withdrawn, making the claims of the captioned application allowable. As such, prosecution of the captioned application was suspended pending declaration of the interference.

Despite the previous withdrawal of all outstanding rejections, however, the instant Office Action was mailed "maintaining" the rejections of the pending claims of the captioned application under 35 U.S.C. §§ 102(e) and 103. The Office Action fails to acknowledge or even mention the August 21, 2000 communication in which the Examiner found the statement under 37 C.F.R. § 1.608(a) acceptable for withdrawal of the rejections and declaration of the interference. Rather, the Office Action merely states that the Second Request was considered, but does not overcome the rejections because an interference cannot be declared without a showing under 37 C.F.R. § 1.608(b).

In "maintaining" the rejections, the Examiner fails to provide any reasoning for why the effective filing dates of the captioned application and the '523 patent, which had

previously been deemed by the Examiner to be within three months of each other, are now found by the same Examiner to be greater than three months apart. Nothing in the instant Office Action explains why the position of the August 21, 2000 Communication is now being reversed.

Absent any explanation by the Examiner to the contrary, it appears, therefore, that the Examiner has now equated the *effective* filing date of a patent or patent application with the *earliest* filing date to which the patent and patent application claim priority. This, however, is improper. Rather than merely being the earliest filing date to which an application claims priority, it is well established that the *effective* filing date of an application is the filing date of the earliest application to which an application claims priority that satisfies the requirements of 35 U.S.C. § 112 for an embodiment within the scope of the count. *Hunt v. Treppschuh*, 187 USPQ 426, 429 (C.C.P.A. 1975); *Weil v. Fritz*, 196 USPQ 600, 608 n.16 (C.C.P.A. 1978).

**The Examiner Has Failed to Provide Any Reasons Why
the Effective Filing Dates of the '523 Patent and the Captioned Application
Have Now Been Deemed to be Greater Than Three Months Apart**

The M.P.E.P. points out that it is unusual to reject a previously allowed claim (M.P.E.P. § 706.04; Eighth Edition, August 2001) and states that great care should be exercised in authorizing rejection of a claim previously noted as allowable. *Id.* In fact, “[c]laims that have once been allowed should not ordinarily be reconsidered unless new art is found or a *manifest mistake* has been made” *Ex parte Grier*, 1923 C.D. 27, 309 O.G. 223 (Comm’r Pat. 1923) (emphasis added).

The M.P.E.P. further states very clearly that “[t]he goal of examination is to *clearly articulate* any rejection . . . so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely” M.P.E.P. § 706 (emphasis added). The

M.P.E.P. also states that “[i]t is important for an examiner to *properly communicate the basis for a rejection* so that the issues can be identified early and the applicant can be given fair opportunity to reply.” M.P.E.P. § 706.02(j) (emphasis added). It explains that “[s]ince patent examiners cannot normally be compelled to testify in legal proceedings regarding their mental processes, *it is important that the written record clearly explain the rationale for decisions made during prosecution of the application.*” *Id.* (emphasis added). The M.P.E.P. also directs that “[t]he record of the file . . . must speak for itself.” M.P.E.P. § 1701.

With respect to an interference between a patent and a patent application, a statement by Applicants or Applicants’ attorney or agent of record under 37 C.F.R. § 1.608(a) that there is a basis upon which Applicants for the patent application are entitled to a judgment relative to the patentee is proper if the effective filing date of the patent application is three months or less after the effective filing date of the patent. 37 C.F.R. § 1.608(a). When an Applicant attempts to provoke an interference with a patent, the Examiner is required to determine the *effective* filing dates of application and the patent. M.P.E.P. § 2308.01 (emphasis added).

In this particular instance, the Examiner had already determined that a showing under 37 C.F.R. § 1.608(a) was acceptable, *i.e.*, that the effective filing dates of the ’523 patent and the captioned application for the proposed count are, indeed, within three months of each other. With the instant Office Action, however, the Examiner “maintains” the previous rejections by contending that the effective filing dates of the two cases are greater than three months apart. Applicants respectfully submit that a rejection cannot be “maintained” when it had already been withdrawn by the Examiner.

As summarized above, the Examiner has failed to provide reasoning for either the reconsideration of Applicants’ reasoning of record or for why the effective filing dates are greater than three months apart. Absent an Examiner statement providing such reasoning,

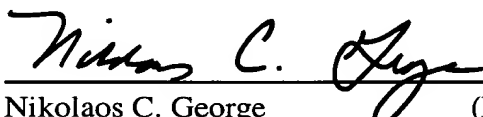
Applicants assert that the Examiner's previous determination remains proper, *i.e.*, that the statement under 37 C.F.R. § 1.608(a), of record, is sufficient and, as such, the requested interference between the '523 patent and the captioned application should be declared.

CONCLUSION

For the reasons of record and summarized herein, the Examiner had previously determined that the effective filing dates of the captioned application and the '523 patent for the proposed count are within three months of each other, making a statement under 37 C.F.R. § 1.608(a) sufficient for declaration of the interference being sought. In the instant Office Action, the Examiner has provided no reasoning for reversing this previous determination of the effective filing dates. Without such reasoning, Applicants assert that the statement under 37 C.F.R. § 1.608(a), of record and previously accepted by the Examiner, remains adequate for declaration of the interference between the captioned application and the '523 patent.

Respectfully submitted,

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